

A11. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K122520

1. Submitter's Identification:

TaiDoc Technology Corporation

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Correspondence:

Pinjung Chen

Regulatory Affairs Specialist

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Date of submission: July 31th, 2012

2. Device name:

Proprietary name: Digital Thermometer, model TD-1001

Regulatory information:

- A. Regulation section: 21 CFR 880.2910
- B. Classification: Class II
- C. Product Code: FLL, Clinical electronic thermometer
- D. Panel: General Hospital (80)

3. Intended Use:

TD-1001 Digital Thermometer is intended to measure the body temperature orally and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.

4. Device Description:

The Digital Thermometer TD-1001 enables easy and accurate readings over the body temperature range. It must be used in conjunction with a disposable probe cover when taking temperature.

From the construction point of view, the digital thermometer comprises of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

Substantial Equivalence Information:

A. Predicate device name:

Omron electronic thermometer Models MC-246

B. Predicate K number: K091676

C. Comparison with predicate:

The Digital Thermometer, model TD-1001, has the following similarities to the predicate device:

- Same intended use.
- Same operating principle and technological characteristics.
- Same measurement area (oral)
- Same functions and accuracy specification.
- Same battery type.

The differences:

- Temperature displayed range
- Operating temperature range
- Storage temperature range
- Battery life

5. Test Principle:

The Digital thermometer TD-1001 is the electronic thermometer operated by a thermistor as the temperature sensor and an ASIC (Application Specified IC) for

signal processing. The basic operation principle is that a change of thermistor, caused by changes of temperature, provide signal to ASIC. ASIC gets the sensor's signal then processes the signal and calculates the result, after that displays the temperature result by a LCD.

6. Performance Characteristics:

The Digital thermometer TD-1001 was validated by the tests according to ASTM E1112-00:2011 standard and met the requirements of prEN12470-3:2000 standard.

A brief description for each test was given in this section. Table 1 lists items of tests, related standard complied and format of data presentation.

Table 1. Summary of test

Item	Standard complied	Data presentation	Attachment
Display temperature range	ASTM E1112-00:2011	Measurement error	4.1.1
Laboratory accuracy	ASTM E1112-00:2011	Measurement error	4.1.2
Operating range	ASTM E1112-00:2011	Measurement error	4.1.3
Storage environment test	ASTM E1112-00:2011	Measurement error	4.1.4
Shock test	ASTM E1112-00:2011	Measurement error	4.1.5
Water resistant test	ASTM E1112-00:2011	Measurement error	4.1.6
Cleaning procedure test	ASTM E1112-00:2011	Measurement error	4.1.7
Software validation	ISO 14971:2007	Verification and validation of TD-1001 software	4.2
Clinical accuracy	prEN12470-3:2000	Clinical bias Clinical repeatability	4.3
Safety	IEC 60601-1	Evaluated by SGS	4.4
Electromagnetic compatibility (EMC)	IEC 60601-1-2	Evaluated by SGS	4.5

7. Conclusion:

Based on the information provided in this submission, TD-1001 Digital thermometer is shown to be substantially equivalent to the predicate Omron electronic thermometer Models MC-246.

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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 5, 2013

Ms. Pinjung Chen
Regulatory Affairs Specialist
Taidoc Technology Corporation
6F, No. 127, Wugong 2nd Road
Wugu District
New Taipei City,
Taiwan 24888

Re: K122520

Trade/Device Name: Digital Thermometer, model TD-1001
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: January 15, 2013
Received: January 22, 2013

Dear Ms. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson".

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A0. Indications for Use

Indications for Use

510(k) Number: K122520

Device Name: Digital Thermometer, model TD-1001

Indications for Use:

TD-1001 Digital Thermometer is intended to measure the body temperature orally and to be used by medical professionals in clinical and hospital environments and consumers in a home environment. It is intended for use on people of all ages.

Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or
Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation (ODE)
510(k) K122520

Page 1 of 1

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
On behalf of U.S. Government, on behalf of,
and on behalf of Person named Sajjad H. Syed.
09/22/2015 10:20:00 AM ET
Serial number: 1461742
Date: 2015-02-25 11:28:03 -0500

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122520